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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/020,798	11/30/2001	Siu Man L. Cowan	22112(2)	9511

7590

08/22/2002

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EXAMINER

PRYOR, ALTON NATHANIEL

ART UNIT

PAPER NUMBER

1616

DATE MAILED: 08/22/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
10/020,798

Applicant(s)
Cowan et al

Examiner
Alton Pryor

Art Unit
1616



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 2 6) ☐ Other:

Art Unit: 1616

Claim Rejections under 35 U.S.C. 102(b) and 103(a)

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1,5,6 are rejected under 35 U.S.C. 102(b) as being anticipated by Adjei et al (US 4851211; 7/25/89). Adjei teaches an aerosol formulation comprising organic solvent (ethanol), a luteinizing hormone (protein) suspended in ethanol, and lipophilic counterion (derivatized carbohydrate). See column 2 line 7 - column 5 line 51.

3. Claims 1,5,6,14 are rejected under 35 U.S.C. 102(b) as being anticipated by Ban et al (HU 62473; 5/28/93). Ban teaches an aerosol formulation comprising organic solvent (ethanol), a osetrogenic hormone (protein) suspended in ethanol or in polypropylene glycol and 1-amyl-nitrite (derivatized carbohydrate). See abstract.

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 2-4,10-13,15 are rejected under 35 U.S.C. 103(a) as being unpatentable over

Art Unit: 1616

Adjei as described above. See 35 U.S.C. 102(b) rejection above. Adjei recites all that is in claims 2,8,9,14-17,19 except for the aerosol comprising the instant amounts of ingredients and instant particle sizes. One having ordinary skill in the art would have been expected to determine the optimum amounts of ingredients and optimum particle sizes through routine experimentation. One would have been motivated to do this in order to develop the most effective aerosol.

6. Claims 2-4,10-13,15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ban as described above. See 35 U.S.C. 102(b) rejection above. Ban recites all that is in claims 2,8,9,14-17,19 except for the aerosol comprising the instant amounts of ingredients and instant particle sizes. One having ordinary skill in the art would have been expected to determine the optimum amounts of ingredients and optimum particle sizes through routine experimentation. One would have been motivated to do this in order to develop the most effective aerosol.

Claim Objection

Claims 7-9 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The prior art does not teach or suggest instant aerosol comprising insulin or cytokine. Claims 16-33 are allowable. The prior art does not teach or suggest a method of applying instant aerosol to respiratory tract.

Telephonic Inquiry


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alton Pryor whose telephone number is (703) 308-4691. The examiner

Art Unit: 1616

can normally be reached on Monday through Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees, can be reached on (703) 308-4628. The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

A handwritten signature in black ink, appearing to read 'Alton Pryor', with a stylized, cursive script.

Alton Pryor

Primary Examiner, AU 1616

8/21/02